



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Conflict of Interest

Conflict of Interest

Effective Date: June 1, 2004
Original Approval Date: June 1, 2004
Revision Date: December 12, 2005
December 1, 2006
June 10, 2010
July 1, 2011
March 1, 2015
July 1, 2015
January 29, 2016
June 8, 2017

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

Michele Kennett

Table of Contents

Purpose

Scope

Policy/Procedure

General Information

Direct Financial Relationships

Indirect Non-financial Interests

Financial Interest Related to the Research

Board member and Consultant conflict

Investigator or other study staff conflicts

Additional Information

1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for conflict of interest.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

General Information

An institution may face a conflict among its multiple duties to protect human subjects. To ensure the integrity of research and its compliance with applicable laws and regulations, and the institution's legitimate interest in the financial health and economic viability of the enterprise, institutions should ensure that the responsibility for human subjects research does not overlap or coincide with responsibility for those institutional financial interests that may be directly affected by the outcome of the research. Institutions should ensure that the functions and administrative responsibilities related to human subjects' research are separate from those related to investment management and technology licensing.

A. Investigator/Research Team Conflicts

Conflicts of Interest may be either financial or non-financial, indirect or direct interests. Conflicts of interest are not always prohibited because not all interests cause conflicts that impact research. Conflicts must be managed or eliminated so that they do not adversely affect participant protections or the credibility of the human research protections program.

When investigators have specific financial relationships or other non-financial interests in research the disclosure must be forwarded to the Conflict of Interest committee for review http://research.missouri.edu/compliance/conflict_of_interest/index.php . The Conflict of Interest committee will evaluate the conflict.

Financial Relationships

Institutions and individuals involved in human subjects' research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property. When a financial interest is disclosed, the disclosure is forwarded to the Conflict of Interest committee for review.

Non-financial Interests

Private interests in outside organizations can result in COI. Examples of private interests include unpaid leadership positions, membership on the board of directors, companies, clubs, societies and organizations such as trade unions and voluntary organizations, which members of the public might reasonably think could influence the decision-making

process. When such non-financial interests are disclosed, the disclosure is forwarded to the Conflict of Interest committee for review.

Investigator or other study staff conflicts:

Any investigator or other person responsible for the design, conduct, or reporting of research (to include spouses and dependent children) that may have a conflict of interest with any proposed research will be forwarded to the Conflict of Interest Committee.

Each investigator shall disclose to the COI committee all interests:

1. That would reasonably appear to be directly and significantly affected by the funded research or educational activities; or
2. The following financial interests of all individuals involved in the design, conduct, or reporting of the research and their spouses and dependent children must be disclosed:
 - Ownership interest, stock options, or other financial interest related to the research of any amount.
 - Compensation related to the research of any amount.
 - Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
 - Board or executive relationship related to the research, regardless of compensation.

This information must be disclosed:

- A. at the time the IRB proposal is submitted;
- B. on an annual basis during the project annual renewal; and
- C. immediately, as new conflicts arise.

If VA regulations apply, researchers must disclose conflicts of interest. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that might affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.

The Conflict of Interest Committee, under the auspices of the Chancellor, independently determines whether the COI can be effectively managed, reduced or eliminated. The IRB also reviews the conflict and has final authority to decide whether the conflicting interest and management plan allows the research to be approved.

Examples of how conflicts of interest might be addressed include the following:

- Public disclosure of significant interests via the consent process

- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research
- Divestiture of significant interests

B. Board member and Consultant conflict:

No IRB member, their spouse or dependent children or consultant may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB member (their spouse and dependent children) or consultant is considered to have a conflicting interest when any of the following are true:

- There is ownership interest, stock options, or other financial interest related to the research.
- They receive compensation related to the research.
- They have a proprietary interest related to the research.
- There is an executive relationship related to the research.
- Involvement in the design, conduct, or reporting of the research.
- When assisting in development of the study
- When there is a personal or professional conflict with the other members listed on the study
- The IRB member or consultant believes that will be unable to impartially review a research protocol.
- Or if the IRB member has identified him or her self for any other reason as having a conflicting interest.

IRB staff will remind members of conflict of interest policies at each meeting.

Educational materials are available for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects' research.

Each board member has the responsibility of making the IRB staff aware of a conflict of interest. Prior to any review assignments, **the IRB staff will check for any potential conflict of interest. The conflict of interest policy applies to each board member for all types of reviews.**

IRB staff will ask the consultant about conflicts prior to review assignment.

Any member (including chairs) that has a conflict of interest with any research reviewed by the Board must excuse him/herself from the meeting prior to any discussion of the project and during the vote. The member may be invited into the meeting to answer

questions; however the member will be excused during the Board deliberations. If a chair is excused from the meeting due to a possible COI, a board member will take over the deliberations for that particular project in the absence of the chair.

If a member is excused from the meeting due to a conflict of interest, a valid quorum must be present or the meeting must be terminated from further action until a valid quorum is obtained.

Additional information

The University of Missouri-Columbia has several policies governing COI:

- Business Policy and Procedures on COI:
<http://www.umsystem.edu/ums/departments/fa/management/business/manual/0102.shtml>
- Collected Rules and Regulations on COI:
<http://www.umsystem.edu/ums/departments/gc/rules/personnel/330/015.shtml>
- Collected Rules and Regulations on Institutional Conflicts of Interest:
<http://www.umsystem.edu/ums/departments/gc/rules/research/410/020.shtml>

[Return to Table of Contents](#)